IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventors	:	Gary W. Wood
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Title	:	COMPOSITION AND METHOD OF CANCER ANTIGEN IMMUNOTHERAPY
Group/Art Unit	:	1642
Examiner	:	Alana M. Harris, Ph.D.
Confirmation No.	:	5012
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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF GARY WOOD

I, Gary Wood, declare as follows:

1. I am the sole inventor of the subject matter claimed in the above-identified patent application.

2. I received a Bachelor of Arts degree in Biology in 1963 from Kalamazoo College, Kalamazoo, MI. I received a Master of Science degree in Microbiology in 1965 from The University of Michigan, Ann Arbor, MI. I received a Ph.D. degree in Microbiology/Immunology in 1971 from the State University of New York at Buffalo, Buffalo, NY.

3. I received post-doctoral training in cancer research from 1971-1973 at the University of Kansas Medical Center, Kansas City, KS. I was employed as a cancer scientist in the Department of Pathology at the University of Kansas Medical Center from 1973-1997. I was employed as a cancer scientist in the Department of Medicine and the Karmanos Cancer Center at Wayne State University from 1997 to 2000. I have authored more than 100 peer-reviewed scientific publications most of them in the area of cancer. I have been

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I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on:

Date: November 26, 2003
Signature: Lora Gurley
Printed Name: Lora Gurley

The Director is hereby authorized to charge any additional amount required, or credit any overpayment, to Deposit Account No. 19-4409.

100 peer-reviewed scientific publications most of them in the area of cancer. I have been the Principal Investigator on multiple cancer grants. I have been the Principal Investigator of several cancer clinical trials. I have been the Principal Investigator of INDs authorizing cancer clinical trials with the Food and Drug Administration.

4. FIGs. 1-3 represent neuroimaging studies demonstrating radiological responses of patients having astrocytoma/ependymoma treated with a combination of autologous cancer cell /GM-CSF vaccination and adoptive transfer of anti-CD3 stimulated peripheral blood T cells in accordance with the present invention.

5. Table 1 represents unpublished data showing the clinical responses of ten patients having renal cell carcinoma being treated with a combination of autologous cancer cell /GM-CSF vaccination and adoptive transfer of anti-CD3 stimulated peripheral blood T cells in accordance with the present invention.

6. In general, the chance of seeing a clinical effect against human grade III and IV astrocytomas already is low at the time of diagnosis, because malignant brain cancers are virtually untreatable. The probability of seeing a clinical effect in the trials of the present invention is further reduced because the trials were limited to patients whose cancers had grown back after initial surgery, radiation and chemotherapy. Because all treated patients had recurrent brain malignancy, the results in this patient population is unexpected.

7. FIG. 4 represents unpublished imaging studies of a patent having renal cell carcinoma in which the cancer had mestastasized into the lungs after being treated with a combination of autologous cancer cell /GM-CSF vaccination and adoptive transfer of anti-CD3 stimulated peripheral blood T cells in accordance with the present invention.

8. Human renal cell carcinoma clinical trials were performed with patients who had advanced stage IV (metastatic) renal cell carcinoma. Stage IV renal cell carcinoma is generally regarded as being untreatable. Because all treated patients had stage III or IV renal cell carcinoma, the results in this patient population is unexpected.

9. Overall, the advantages of treating patients with combination of autologous cancer cell / GM-CSF vaccination and adoptive transfer of anti-CD3 stimulated peripheral blood T cells in accordance with the present invention were much greater than would have been predicted. In fact, it was surprising that there was any advantage at all.

10. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above-referenced application or any patent issuing thereon.

Date: 11/24/2003 By: